

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences**

In re Patent Application of

BERTHON-JONES et al.

Atty. Ref.: JPD-4398-427

Serial No. 10/533,928

TC/A.U.: 3771

Filed: July 29, 2005

Examiner: Clinton Ostrup

For: MASK AND COMPONENTS THEREOF

* * * * *

March 8, 2010

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

In reply to Appellants' arguments that Amarasinghe et al. (WO 02/45784) do not anticipate claim 19 because Amarasinghe et al. do not disclose or suggest, at least, at least one selective frame portion engaged with a cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body of the frame, the Examiner's Answer on page 9, third paragraph, states that "the brace (12) is structured to engage the cushion (16) via shell (13) and tightening of the straps." The Examiner's Answer further states that "the tightness of the cushion would inherently be adjusted via the straps connected to brace (12). See: page 5, lines 14-19 of Amarasinghe." The Examiner's Answer concludes that "upon positive pressure being applied to the mask, a pressure differential would inherently be created and by the mask

being strapped to a patient (Figure 2) the cushion would inherently apply a force to the patient by virtue of it being strapped to the patient. This pressure applied to a patient would then either be increased or decreased by tightening or loosening of the straps connected to the brace (12).”

With respect to the conclusion that the brace 12 of Amarasinghe et al. is structured to engage the cushion 16 via the mask shell 13, it is respectfully noted that claim 19 recites that the at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. Claim 19 does not recite that the at least one selected frame portion is engaged with the cushion via other elements of the mask assembly as consistently, and incorrectly, interpreted in the Examiner’s Answer.

As noted in the Appeal Brief, the standard of anticipation under 35 U.S.C. §102 is identity of invention. As noted in MPEP §2111, during examination, the claims are to be given the broadest reasonable interpretation consistent with the specification, and consistent with the interpretation that would be reached by one of ordinary skill in the art. It is respectfully submitted that the interpretation given to claim 19, including for example, the various dictionary definitions of the term “engaged” relied upon by the examiner throughout prosecution, is not the broadest reasonable interpretation of claim 19 consistent with the specification, and consistent with the interpretation that would be reached by one of ordinary skill in the art.

With respect to the conclusions in the Examiner’s Answer on page 9, third paragraph, that the tightness of the cushion would inherently be adjusted via the straps

connected to the brace 12 of Amarasinghe et al., and that upon positive pressure being applied to the mask, a pressure differential would inherently be created and by the mask being strapped to a patient the cushion would inherently apply a force to the patient by virtue of it being strapped to the patient, it is respectfully noted that claim 19 recites that the cushion, upon application of positive pressure, applies a force to the patient and the force is adjustable in accordance with 1) the position of the at least one selected frame portion relative to the main body for a given value of the positive pressure, and/or 2) variations in the positive pressure. In other words, claim 19 recites that it is the position of the at least one selected frame portion and/or variations in the positive pressure, not the tightness or looseness of the straps of the headgear, that adjust the force applied to the patient by the cushion upon application of positive pressure. Accordingly, even assuming that tightening or loosening of the straps of Amarasinghe et al. would inherently apply, or adjust, a force applied to the patient, such an interpretation of the reference would still fail to present a *prima facie* case of anticipation as such an interpretation would fail to disclose the identical invention recited in claim 19.

It is also respectfully submitted that page 5, lines 4-19, of Amarasinghe et al. are not substantial evidence that the reference discloses the identical invention recited in claim 19. Page 5, lines 4-19, of Amarasinghe et al. merely summarizes the invention of Amarasinghe et al. and does not provide the required basis in fact and/or technical reasoning required to support the numerous reliances on the theory of inherency found on page 9, third paragraph, of the Examiner's Answer.

With respect to the assertions on the paragraph bridging pages 9-10 of the Examiner's Answer that the brace 12 of Amarasinghe et al. is "wrapped around" the cushion 16, it is respectfully noted that the reference to Fig. 2 of Amarasinghe et al. is the only support provided for the conclusion that the brace 12 engages the cushion 16 in the manner recited in claim 19, giving the claim its broadest reasonable interpretation. However, Fig. 2 of Amarasinghe et al. does not provide substantial evidence that the identical invention is disclosed by the reference.

Throughout the prosecution of the application the examiner has alleged that Fig. 2 of Amarasinghe et al. "specifically shows portions (15) of brace (12) wrapping around the cushion (16)." See, for example, page 9, lines 10-11, of the Examiner's Answer. Fig. 2 of Amarasinghe et al. shows no such thing. As noted by Appellants in previous replies, as shown in Fig. 3, and in particular Fig. 4, of Amarasinghe et al., the brace 12, including the strap attachment points 15, is fitted between the existing mask frame headgear attachment points 17 of the mask shell 13 and the mask shell out surface, i.e. the peripheral flange portion 18. See page 6, lines 29-31, of Amarasinghe et al. As clearly shown in Fig. 4, the attachment points 15 of the brace 12 do not "wrap around" the cushion 16.

With respect to the disclosure on page 8, lines 8-16, of Amarasinghe et al., this passage merely discloses that the brace 12 may be configured to engage brace receiving features that may be provided by a mask cushion clip. There is nothing in this passage of the reference that discloses, or even suggests, the identical invention recited in claim 19. Furthermore, a cushion clip, as would be understood by one of ordinary skill in the art, is

an element that is provided to a mask to secure the cushion to the frame (shell). Once secured to the frame (shell), the cushion clip is not adjustable relative to the frame (shell). Accordingly, even assuming a portion of the brace 12 of Amarasinghe et al. were engaged with the cushion clip, adjustment of the brace 12, or any portion thereof, with respect to the cushion clip or mask shell 13 would not adjust the cushion 16.

With respect to the reminder on page 11, lines 5-12, of the Examiner's Answer of Appellants' agreement that claim 19 does not require the frame portion being directly in contact with the cushion, it is respectfully noted that it is not the examiner's interpretation of Amarasinghe et al. that the brace 12 directly contacts the cushion 16. The examiner's interpretation of Amarasinghe et al. is on page 9, third paragraph, of the Examiner's Answer which states that the brace 12 is engaged with the cushion via the headgear straps and the mask shell 13 and that the cushion would inherently be adjusted via the straps connected to the brace. However, as noted above, claim 19 recites that the cushion applies a force to the patient and the force is adjustable in accordance with the position of the at least one selected frame portion relative to the main body and/or variations in the positive pressure. Tightening or loosening of the straps of Amarasinghe et al., as interpreted by the examiner, is not the identical invention recited in claim 19.

With respect to claim 34, the Examiner's Answer on page 15, lines 3-16, asserts that claim 34 does not require the lateral sides be bent, only that they are capable of being bent. The Examiner's Answer concludes that Amarasinghe et al. clearly teach side projecting members (attachment points 15) that are capable of being bent to cause each

lateral side of the frame to push against sides of the cushion. The Office Action cites Figs. 2-4 of Amarasinghe et al.

It is respectfully submitted that there is nothing in the disclosure of Figs. 2-4, including the description of these figures, that identically discloses the invention recited in claim 34. In fact, it is respectfully submitted that it is clear from the description of, at least, Figs. 3 and 4, that Amarasinghe et al. do not disclose the identical invention recited in claim 34.

As disclosed on page 6, lines 29-31, of Amarasinghe et al., and as shown in Figs. 3 and 4, the brace 12 is fitted between the existing mask frame headgear attachment points 17 and the mask shell outer surface, and in the case shown in Fig. 3 the peripheral flange portion 18 of the mask shell 13. As clearly shown in Figs. 3 and 4, the peripheral flange portion 18 of the mask shell 13 is provided between the attachment points 15 of the brace 12 and the cushion 16. Accordingly, the attachment points 15 of the brace 12 of Amarasinghe et al. are not capable of being bent to cause each lateral side of the frame (mask shell 13) to push against the sides of the cushion 16. The mask shell 13 of Amarasinghe et al., including the peripheral flange portion 18, is rigid (e.g. made out of polycarbonate). Bending the attachment points 15 of the brace 12 will not cause each lateral side of the mask shell 13 to push against the sides of the cushion 16.

In response to Appellants' arguments traversing the rejection under 35 U.S.C. §103(a) over Amarasinghe et al. in view of Gradon et al. (U.S. Patent Application Publication 2003/0089373 A1), the Examiner's Answer on page 18, first paragraph, states that the test for obvious is not whether the features of a secondary reference may be

bodily incorporated into the structure of a primary reference. The Examiner's Answer concludes that in the instant case, "it is clear that the adjustment knob of Gradon would provide for quick and easy adjustment of the forehead stabilization portion without having to remove the straps." However, as noted on page 32, second full paragraph, of the Appeal Brief, Amarasinghe et al. disclose on page 9, lines 1-6, that by making the mask brace 12 of malleable material, the user can make some adjustment to the position of the headgear retaining portion (i.e. the attachment points 15) and/or of the mask stabilizing feature (i.e. the stabilizing portion 20) for rapid tailoring of the mask assembly to a user's particular requirements. As was also noted in the Appeal Brief, Gradon et al. disclose in paragraph [0053] that the knob 440 must be loosened and tightened in order to affect adjustment of the bridge member 430. It is simply illogical that one of ordinary skill in the art would replace the "rapid tailoring" of the mask assembly of Amarasinghe et al. with the loosening, adjusting, and tightening required by Gradon et al.

The Examiner's Answer on page 18, lines 11-18, alleges that Appellants' arguments regarding the combination of Amarasinghe et al. and Gradon et al. have not been found convincing as the bending of the brace 12 of Amarasinghe et al. would require the removal of the straps. However, there is nothing in the disclosure of Amarasinghe et al. that suggests that the straps must be removed from the brace 12 in order to bend the attachment points 15 or the stabilizing portion 20 of the brace 12 to adjust the position of the headgear retaining portions.

In response to Appellants' arguments regarding the combination of Amarasinghe et al. and Hellings et al. (U.S. Patent 5,975,079), the Examiner's Answer on page 19,

lines 14-21, states “the examiner maintains that the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate (which would change the force applied to the patient, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.”

The “stiffening rate” of the cushion (i.e. the sealing material 7) of Hellings et al. is determined by the amount of air supplied to the nipple 12 by the air pump that enables inflation of the soft pliable material 11. See column 3, lines 6-12. The “stiffening rate” of the cushion of Hellings et al. is not adjusted by the rate the gas is supplied to the mask through the portal 13 located on the mask and used for the introduction of various gases, such as oxygen, nitrogen and other anesthetic gases or the like. Adjusting the rate at which gases are supplied to the portal 13 will have not any effect on the “stiffening rate” of the cushion (sealing material 7) of Hellings et al.

For the above reasons, it is believed that the application is in clear condition for allowance; therefore, early reversal of the rejections and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /John P. Darling/
John P. Darling
Reg. No. 44,482

JPD:tlm
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100